

5168. Cal-Fer-D tablets. (F. D. C. No. 38986. S. No. 22-974 M.)

QUANTITY: 34 100-tablet btl. at Boston, Mass., in possession of Pitman-Moore Co.

SHIPPED: 5-3-55, from Indianapolis, Ind.

LABEL IN PART: (Btl.) "Tablets Cal-Fer-D Coated Red Each tablet represents: * * * Vitamin D (Irradiated Ergosterol) . . . 200 U. S. P. units."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 50 percent of the declared amount of vitamin D.

LIBELED: 3-8-56, Dist. Mass.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each tablet represents: * * * Vitamin D (Irradiated Ergosterol) . . . 200 U. S. P. units" was false and misleading.

DISPOSITION: 6-19-56. Default—destruction.

5169. Magnesium carbonate. (F. D. C. No. 39281. S. No. 31-340 M.)

QUANTITY: 6 50-lb. bags at Cincinnati, Ohio.

SHIPPED: 4-11-56, from Philadelphia, Pa., by Darlington Chemicals, Inc.

LABEL IN PART: (Bag) "Magnesium Oxide Light Powder * * * Darlington Chemicals (Inc.) Philadelphia, Pa. Made in England"; (sticker) "DCI Magnesium Carbonate U. S. P."

RESULTS OF INVESTIGATION: Analysis showed that the article was magnesium oxide with a small amount of calcium oxide.

LIBELED: 6-18-56, S. Dist. Ohio.

CHARGE: 501 (d)—when shipped, magnesium oxide with a small amount of calcium oxide had been substituted for *magnesium carbonate*; and 502 (a)—the label statement "DCI Magnesium Carbonate U. S. P." was false and misleading.

DISPOSITION: 7-17-56. Default—destruction.

5170. Ephedrine sulfate. (F. D. C. No. 39006. S. No. 47-632 M.)

QUANTITY: 1 case containing 2 100-oz. cans, and 1 500-oz. drum at New York, N. Y.

SHIPPED: 1-31-56, from England.

RESULTS OF INVESTIGATION: The article was water-damaged in shipment.

LIBELED: 4-3-56, S. Dist. N. Y.

CHARGE: 501 (b), while held for sale, the quality and purity of the article fell below the standard set forth in the United States Pharmacopeia since the standard provides that *ephedrine sulfate* when dried at 105° for 3 hours, loses not more than 2 percent of its weight; whereas the article when dried at 105° for 3 hours, would lose substantially more than 2 percent of its weight because of excessive water content.

DISPOSITION: 4-24-56. Default—destruction.

5171. Digitalis tablets. (F. D. C. No. 38985. S. No. 23-877 M.)

QUANTITY: 1 drum containing 24,000 tablets at Tucson, Ariz.

SHIPPED: 12-29-55, from Denver, Colo., by Western Research Laboratories.

RESULTS OF INVESTIGATION: Analysis showed that the digitalis potency of the article was less than 85 percent of its declared potency of 1½ grains of U. S. P.

digitalis per tablet. The United States Pharmacopeia provides that the potency of digitalis calculated from the prescribed assay is satisfactory if the result is not less than 85 percent and not more than 120 percent of the labeled potency.

LIBELED: 3-14-56, Dist. Ariz.

CHARGE: 501 (b)—the strength of the article, when shipped, differed from the standard for such article as set forth in the U. S. Pharmacopeia; and 502 (a)—the label statement "Each Tablet Contains: Digitalis, U. S. P.—1½ gr." was false and misleading.

DISPOSITION: 4-30-56. Default—destruction.

5172. Digitalis tablets. (F. D. C. No. 39237. S. No. 37-667 M.)

QUANTITY: 12 1,000-tablet btls. and 2 500-tablet btls. at Buffalo, N. Y.

SHIPPED: 3-27-56, from St. Louis, Mo., by Keith-Victor Pharmacal Co.

LABEL IN PART: "Digitalis 1½ grs. Myocardial Stimulant Each tablet represents Digitalis Leaf 1 U. S. P. Unit * * * Control 264-456 * * * Manufactured for Kloman Inst. Co., Inc. Buffalo, New York."

RESULTS OF INVESTIGATION: The tablets were shipped in interstate commerce in bulk, and upon their receipt by the consignee, were repackaged and relabeled.

Analysis showed that the digitalis potency of the article fell below its professed potency.

LIBELED: 5-15-56, W. Dist. N. Y.

CHARGE: 501 (b)—the article purported to be and was represented as a drug, "Digitalis Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium, and, when shipped, its strength and quality differed from the standard set forth in such compendium; and 502 (a)—the label statement "Digitalis 1½ grs." was false and misleading.

DISPOSITION: 6-20-56. Default—destruction.

5173. Thyroid tablets. (F. D. C. No. 39598. S. No. 55-326 M.)

QUANTITY: 5 5,000-tablet btls. and 28 1,000-tablet btls. at Columbus, Ohio.

SHIPPED: 12-29-55, from Memphis, Tenn., by Morton Pharmaceuticals, Inc.

LABEL IN PART: "Code No. 467 * * * Thyroid Tablets 1 Gr. Code No. 466 E. C. Orange Each Tablet Contains Thyroid 1 Gr. USP * * * Distributed By Standard Medical Supply Co. * * * Columbus, Ohio."

LIBELED: 10-17-56, S. Dist. Ohio.

CHARGE: 501 (b)—the article was represented as a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and, when shipped, it fell below the official standard of quality since it failed to comply with the U. S. P. disintegration test for tablets.

DISPOSITION: 11-21-56. Default—destruction.

5174. Velestron tablets. (F. D. C. No. 39447. S. No. 27-218 M.)

QUANTITY: 52 100-tablet btls. at Birmingham, Ala., in possession of Veltex Co.

SHIPPED: 2-29-56, from St. Louis, Mo., by Victor M. Hermelin & Co.

LABEL IN PART: (Btl.) "100 Tablets Velestron Conjugated Estrogens 1.25 Mg. * * * Each Sugar-Coated Brown Tablet Contains: Naturally-occur-